Serial No.: 09/934,249 - 7 - Art Unit: 1648

Conf. No.: 6506

REMARKS

Applicant respectfully thanks the Examiner for withdrawing a number of rejections due to Applicant's response to the previous Office Action. The specification has been amended to correct two minor typographical errors. In the specification "0.015M sodium citrate" was mistakenly written as "0.15M sodium citrate" and "pyrrolidone" was mistakenly written as "pyrolidone". Stringent conditions used in the hybridization of nucleic acids are well known in the art and may be found in references such as Molecular Cloning: A Laboratory Manual, J. Sambrook, et al., eds., Second Edition, Cold Spring Harbor Laboratory Press, Cold Spring Harbor, New York, 1989 and Current Protocols in Molecular Biology, F.M. Ausubel, et al., eds., John Wiley & Sons, Inc., New York provided in the specification on page 14, lines 8-11. These mistakes are corrected herewith. Claims 1-4, 8-11, 68, 80-84 and 86-88 are pending for examination with claims 1 and 4 being independent claims. Claims 1, 4 and 80 have been amended. Claim 1 has been amended to further define the hybridization conditions previously added to the claim. Support for the amendments can be found in the specification on page 14, lines 12-18. Claim 4 have been amended to remove "unique" as well as the limitation regarding the exclusion of particular sequences. Claim 80 has also been amended to remove the term "unique". Support for these claim amendments can be found throughout the specification, particularly on page 2, lines 29-31; page 3, lines 13-17 and in the claims as originally filed. Claims 79 and 85 are canceled herewith. No new matter has been added.

Rejections Under 35 U.S.C. §112

The Examiner has rejected claims 1, 8 and 10 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner maintains that the claims do not clearly define highly stringent hybridization conditions.

Applicant has amended claim 1 to more clearly define the hybridization conditions. The claim as amended no longer contains a parenthetical statement and also includes wash conditions. Applicant asserts that the claims as amended clearly defines highly stringent hybridization conditions and, therefore, obviate the rejection of claims 1, 8 and 10 under 35 U.S.C. §112 for being indefinite.

Serial No.: 09/934,249 - 8 - Art Unit: 1648

Conf. No.: 6506

Accordingly, withdrawal of this rejection is respectfully requested.

The Examiner has also rejected claims 4, 9, 11, 79-81 and 84-88 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. The Examiner bases the rejection of these claims on the term "unique fragment". The Examiner maintains that Applicant has not provided adequate information regarding the content of the prior art and, therefore, what is or is not covered by the claims.

Although Applicant respectfully disagrees with the rejection of the claims on this basis, Applicant has amended claims 4 and 80 to remove "unique" in order to expedite the further prosecution of this application. Applicant believes that this amendment is sufficient to obviate the rejection of these claims.

Accordingly, withdrawal of the rejection of claims 4, 9, 11, 79-81 and 84-88 under 35 U.S.C. §112, second paragraph as being indefinite is respectfully requested.

The Examiner has also rejected claims 3 and 83 under 35 U.S.C. §112, first paragraph as being subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that Applicant was, at the time of the filing of the application, in possession of the invention. The Examiner maintains that anti-apoptotic MIVR-1 polypeptides that are fragments of SEQ ID NO: 3 have not been sufficiently described to show possession of the subject matter of claims 3 and 83.

Although Applicant respectfully disagrees with the Examiner's assessment of the written description and claims, Applicant has amended claim 1, from which claim 3 depends, to remove the functional limitation of the claim in order to expedite the further prosecution of this application. As argued previously, and to which the Examiner has agreed (see p. 6 of the Office Action), the disclosure in Applicant's specification is sufficient to describe any and all fragments of SEQ ID NO: 3. Applicant believes that this amendment is sufficient to obviate the rejection of claims 3 and 83.

Accordingly, withdrawal of the rejection of these claims under 35 U.S.C. §112, first paragraph is respectfully requested.

Serial No.: 09/934,249 - 9 - Art Unit: 1648

Conf. No.: 6506

The Examiner has also rejected claims 1-3, 8, 10, 11, 82 and 83 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to make and/or use the invention. The Examiner argues that the claims read on nucleic acids that code for MIVR-1 polypeptides with anti-apoptotic activity. As such, it is the Examiner's belief that the protein described by Tang et al. in WO 00/34477 provides doubt as to the asserted activity of Applicant's protein. The Examiner further argues that Applicant has not provided sufficient guidance as to what fragments of the sequences provided would code for a polypeptide with the desired anti-apoptotic activity.

Applicant, as before, respectfully disagrees with the Examiner's assessment of the cited reference as well as the guidance provided in Applicant's specification. Firstly, Applicant again asserts that the teachings of Tang et al. do not shed any doubt as to the assertion of the anti-apoptotic activity of Applicant's protein. The teachings of Tang et al. are directed to a different protein even though the proteins share 87% homology according to the Examiner. Such homology is not an automatic indication of the function of the MIVR-1 protein. Additionally, Tang et al. does not demonstrate that Applicant's protein does not have anti-apoptotic activity. Tang et al. does not even demonstrate that their protein does not have anti-apoptotic activity. In fact, it is possible that the neuron-associated protein could be involved with mediating apoptotic activity. Therefore, Applicant maintains that the teachings of Tang et al. are not sufficient for Examiner to doubt the Applicant's assertions.

Furthermore, the Examiner is respectfully reminded that the test for undue experimentation is whether or not the amount of experimentation required to practice the claimed invention is undue. The Examiner in his arguments has not demonstrated how making polypeptides encoded by the fragments of the nucleic acid sequences provided and testing these polypeptides for anti-apoptotic activity requires undue experimentation. In fact, the Examiner admits on page 9 of the Office Action that the quantity of experimentation needed to determine the activity of a fragment may not be undue. Applicant maintains that such experimentation is routine in the art. The Examiner is reminded that the level of skill in the art is extremely high. One of ordinary skill in the art based on their level of skill and the teachings provided in

Serial No.: 09/934,249 - 10 - Art Unit: 1648

Conf. No.: 6506

Applicant's specification would be reasonably expected to be able to make and use MIVR-1 polypeptides. As such, Applicant maintains that the rejected claims are sufficiently enabled.

Although Applicant respectfully disagrees with the Examiner's rejection of the claims for at least the arguments presented above, Applicant has amended claim 1 to remove the functional limitation of the claim in order to expedite the further prosecution of this application. Applicant believes that this amendment is sufficient to obviate the rejection of the claims.

Accordingly, withdrawal of the rejection of claims 1-3, 8, 10, 11, 82 and 83 under 35 U.S.C. §112, first paragraph is respectfully requested.

The Examiner has also rejected claims 4, 9, 11, 79-81, and 84-87 under 35 U.S.C. §112, first paragraph as containing subject matter which was not described in the specification in such a way as to reasonably convey to one of ordinary skill in the art that Applicant at the time the application was filed had possession of the claimed invention. The Examiner maintains that the Applicant has not sufficiently described the characteristics possessed by the unique fragments of the claims to show that Applicant had possession of the fragments of the claims. The Examiner maintains that the Applicant has not provided any more description of the claimed fragments other than what Examiner considers their "function" of being unique.

Applicant again respectfully disagrees with the Examiner for ascribing to the term "unique" a particular function and for concluding that Applicant has not sufficiently described the genus of the claims. Again, Applicant is merely claiming those fragments of SEQ ID NO: 1 and their complements that were not in the prior art at the time of Applicant's filing. As the genus of any and all fragments are necessarily described by providing SEQ ID NO: 1, Applicant maintains that the genus of unique fragments are sufficiently described to show possession of the claimed invention. Nonetheless, in order to expedite the prosecution of this application, Applicant has amended claim 4 and 80 to remove the term "unique". Applicant believes that this amendment is sufficient to obviate the rejection of the claims.

Accordingly, withdrawal of the rejection of claims 4, 9, 11, 79-81, and 84-87 under 35 U.S.C. §112, first paragraph is respectfully requested.

Serial No.: 09/934,249 - 11 - Art Unit: 1648

Conf. No.: 6506

Rejections Under 35 U.S.C. §102

The Examiner rejected claim 1 under 35 U.S.C. §102(a) as being anticipated by either Tang et al. or Xu et al. (Genomics, 66: 257-63, 2000 (Accession No. AF224278)).

As Applicant has amended claim 1 to further define the highly stringent hybridization conditions, Applicant believes the rejection of claim 1 on this basis has been obviated.

Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's representative at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted, *Lee et al.*, *Applicant*

 R_{V}

Janice A. Vatland, Reg. No. 52, 318

Wolf, Greenfield & Sacks, P.C.

600 Atlantic Avenue

Boston, Massachusetts 02210-2206

Telephone: (617) 646-8000

Docket No. P0738.70001US00

Date: April 2, 2004

x04/21/04x